# PATIENT INFORMATION LEAFLET

## SCHEDULING STATUS

S2

## PROPRIETARY NAME AND DOSAGE FORM

RotaTeq® Solution

(rotavirus vaccine, live, oral, pentavalent, MSD)

**Read all of this leaflet carefully before your child is vaccinated.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- RotaTeq has been prescribed for your child and it should not be shared with other people. It may harm them, even if their symptoms are the same as those of your child.

## WHAT RotaTeq CONTAINS

The active ingredients are: Each 2 ml dose contains the following human-bovine rotavirus reassortants: G1, G2, G3, G4 and P1A[8].

The minimum dose levels of the reassortants are as follows:

G1 $2,2 \times 10^6$ infectious units

G2 $2,8 \times 10^6$ infectious units

G3 $2,2 \times 10^6$ infectious units

G4 $2,0 \times 10^6$ infectious units

P1A[8] $2,3 \times 10^6$ infectious units

The other ingredients are: Sucrose, sodium citrate, sodium phosphate monobasic monohydrate, sodium hydroxide, polysorbate 80 and also Low Protein Kidney Medium -3 (LPKM-3) and rotavirus diluent. There are no preservatives or thimerosal present.

Contains sugar (sucrose).

**WHAT RotaTeq IS USED FOR**

RotaTeq is a viral vaccine that helps provide protection for your child against rotavirus infection, a viral infection of the digestive tract and a major cause of gastroenteritis (inflammation of the stomach and intestines which causes diarrhoea and vomiting). Protection is observed to last for at least 2 years. RotaTeq works by helping the body develop natural defences against the most common types or “strains” of rotavirus.

Rotavirus gastroenteritis may cause fever, vomiting and diarrhoea. These symptoms can lead to the loss of body fluids (dehydration) and even to death.

It is the chief cause of severe dehydrating diarrhoea among infants and young children around the world. Before the vaccine was used, the virus was the cause for about 25 million physician visits per year. It also accounted for 2,1 million hospital admissions and 352 000 to 592 000 deaths per year worldwide.

Rotavirus infects the small intestine and usually starts with fever and vomiting, followed by diarrhoea. The diarrhoea can be mild to severe and generally lasts 3 to 9 days. Severe vomiting and diarrhoea (> 5 times each day) lasts an average of 3 to 6 days. Nearly all

children are infected with rotavirus by the time they are 5 years old. This is true even where standards of hygiene are high.

**BEFORE YOU TAKE RotaTeq**

**Who should not be vaccinated with RotaTeq:**

Your child should not get the vaccine if:

- He or she has an allergic reaction after getting a dose of the vaccine.
- He or she is allergic to any of the ingredients of the vaccine. A list of ingredients can be found at the beginning of this leaflet under (**"WHAT RotaTeq CONTAINS"**).
- He or she has Severe Combined Immunodeficiency Disease [SCID]).

**Take special care with RotaTeq:**

There are some things your doctor should know before your child gets the vaccine. You should tell your doctor if your child:

- Has any illness with fever. A mild fever or upper respiratory infection (cold) by itself is not a reason to delay taking the vaccination.
- Has diarrhoea or is vomiting.
- Has not been gaining weight.
- Is not growing as expected.
- Has a blood disorder.
- Has any type of cancer.
- Has an immune system that is weakened because of a disease (this includes HIV infection or AIDS).
- Gets treatment or takes medicines that may weaken the immune system.
- Was born with gastrointestinal problems or has had an intestinal blockage.

- Has regular close contact with a member of the family or household who has a weakened immune system. For example, a person in the house with cancer or one who is taking medicine that may weaken their immune system.

As with other vaccines, RotaTeq may not fully protect all those who get it. Some children may already have the virus but not yet show signs of being sick. In those cases, the vaccine may not be able to prevent the illness.

RotaTeq helps protect against diarrhoea and vomiting only if they are caused by rotavirus. It does not protect against them if they are caused by anything else.

Hand washing is recommended after diaper changes to help prevent the spread of vaccine virus.

**Pregnancy and Breastfeeding**

RotaTeq is a paediatric vaccine not intended for adults and should not be given to pregnant or lactating women. There are no data available on the use during pregnancy or lactation in humans.

**Driving and using machinery:**

RotaTeq is not intended for adults.

**Important information about some of the ingredients of RotaTeq:**

RotaTeq contains sucrose. If you have been told that your child has an intolerance to some sugars, inform your doctor/healthcare professional before the vaccine is administered.

There are no preservatives or thimerosal present.

**Taking other medicines with RotaTeq:**

Giving oral poliovirus vaccine (OPV) at the same time as RotaTeq may reduce some responses to RotaTeq, but a high level of protection against severe rotavirus gastroenteritis is still expected.

**If your child is taking other medicines on a regular basis, including complementary or traditional medicines, the use of RotaTeq with these medicines may cause undesirable interactions.**

Your child may get RotaTeq at the same time as other vaccines, but it should not be mixed with any other vaccines or solutions.

**HOW TO TAKE RotaTeq**

RotaTeq SHOULD ONLY BE ADMINISTERED BY YOUR DOCTOR/HEALTHCARE PROFESSIONAL OR PHARMACIST.

FOR ORAL USE ONLY. NOT FOR INJECTION.

The vaccine is given by mouth and is a series of 3 doses. The first dose is given as early as 6 weeks of age. The next two doses are given one to two months apart.

**If your child receives more than the usual dose of RotaTeq:**

No information is available about overdosage with RotaTeq. However, in the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

**If you forget to have your child vaccinated with RotaTeq:**

Your child needs 3 doses of the vaccine. It is important that you follow the instructions of your healthcare provider regarding your child's return visits for the follow-up doses. It is important to keep those appointments. If you forget or are not able to go back to your healthcare provider at the planned time, ask your healthcare provider for advice.

**POSSIBLE SIDE EFFECTS**

RotaTeq can have side effects.

Not all side effects reported for this vaccine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this vaccine, please consult your doctor, pharmacist or other healthcare professional for advice.

The side effects of RotaTeq are usually mild and do not last long. In addition, these side effects have not been reported much more frequently than when a placebo (an oral solution without vaccine) was given.

The very common side effects reported with the use of RotaTeq were fever, diarrhoea and vomiting. Uncommonly reported were runny nose, sore throat and ear infection. Rarely reported was bronchospasm (wheezing or coughing).


Public disclosed

Other reported side effects include allergic reactions, which may be severe (anaphylaxis), allergic swelling, hives and intussusception (a form of blockage of the bowel in which one segment of bowel becomes enfolded within another segment), the symptoms and signs of which may include severe stomach pain, persistent vomiting, blood in stools, a swollen belly and fever.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

**STORING AND DISPOSING OF RotaTeq**

Keep all medicines out of the reach and sight of children.

Store and transport refrigerated at 2 °C to 8 °C. DO NOT STORE FROZEN. While it is acceptable for the product to freeze during distribution from the manufacturer, the product should be discarded if it freezes during storage. Protect from light. The product must be used before the expiration date.

RotaTeq should be administered as soon as possible after being removed from refrigeration. When out of refrigeration at room temperature at or below 25 °C, administration may be delayed for up to 48 hours.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Discard the empty tube and cap in approved biological waste containers according to local regulations.



Public disclosed

## PRESENTATION OF RotaTeq

RotaTeq is available as a single, pre-filled 2 ml unit dose in a slightly opaque plastic dosing tube with a twist-off cap. The dosing tube is embossed with ROTAVIRUS VACCINE on both sides and is contained in a pouch. The container and delivery system are latex-free.

RotaTeq is available in packs of 1, 10 and 25.

## IDENTIFICATION OF RotaTeq

RotaTeq is a pale, yellow, clear liquid that may have a pink tint.

## REGISTRATION NUMBER

A40/30.1/0730

## NAME AND BUSINESS ADDRESS OF REGISTRATION HOLDER

MSD (Pty) Ltd

117 16th Road

Halfway House

1685

South Africa

Tel No.: (011) 655 3000

## DATE OF PUBLICATION

Date on the registration certificate: 10 August 2007

Date of the most recent revision as approved: 26 November 2015

WPPI-RTV-OS-062013